UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,478	04/16/2007	**Yasuhiro Kuroda**	PHJP040002US	5977

38107 7590 08/30/2010

PHILIPS INTELLECTUAL PROPERTY & STANDARDS
P. O. Box 3001
BRIARCLIFF MANOR, NY 10510

EXAMINER	
CLOW, LORI A	
ART UNIT	**PAPER NUMBER**
1631	
MAIL DATE	**DELIVERY MODE**
08/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,478	KURODA ET AL.	
	Examiner	Art Unit	
	LORI A. CLOW	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/31/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 1-19 are currently pending and under exam herein.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Foreign priority to JP 2004-058749, filed 3 March 2004 is claimed. This Application is a National stage filing of PCT 2005/050729, filed 1 March 2005.

Information Disclosure Statement

The Information Disclosure Statement filed 31 August 2006 has been considered. A signed copy of PTO form 1449 is included with this Office Action.

Drawings

The Drawings submitted 13 August 2006 are accepted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7 and claims dependent therefrom recite, "calculating a total clearance of a drug with due consideration paid to the renal function failure and blood filtering". It is unclear as to the metes and bounds of the phrase "with due consideration". What parameters define a "due consideration"? For example, is a "due consideration" a certain value of renal function failure and blood filtering? Clarification through clearer claim language is requested.

Claims 1, 7, and those claims dependent therefrom recite, "on the basis of the blood filtering information, biological information, and drug information". It is unclear as to what about the "blood filtering, biological information, and drug information" forms a basis to calculate total clearance. Clarification through clearer claim language is requested.

Claims 4 and 10 recite, "wherein the total clearance of the drug is the sum of the renal clearance of the drug and the blood filtering clearance of the drug". The claims are unclear because neither claim 4 nor claim 10 recite the calculation of a renal clearance or a blood filter clearance. Clarification through clearer claim language is requested.

Claim 5 recites, "said displaying means displays a guideline by a level bar as the indication of the renal creatinine clearance". It is unclear as to what context a "guideline as a level bar" appears. Is it, for example, a guideline on a display monitor in which a level bar indicator illustrates creatinine clearance or is it some other display mechanism with a level bar? Clarification through clearer claim language is requested.

Claim 12 and those claims dependent therefrom recite, "providing a dose calculation of the drug based on the total clearance of the drug". It is unclear as to what about the dose calculation is based on the total clearance of the drug. What parameters of total clearance lead

one to provide a dose calculation? Are there certain values that represent certain dosages, for example? Clarification through clearer claim language is requested.

Claim 15 recites, "wherein said retrieving blood filtering information, biological information, and drug information is used in calculating the total clearance of the drug". It is unclear as to how "retrieving" can be used in "calculating". Perhaps Applicant intends the claim to read, "wherein said information retrieval is used in calculating the total clearance of the drug". Clarification through clearer claim language is requested.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7-18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 7-11 recite "a program operable in a computer". A computer program product is drawn to non-statutory subject matter because a computer product reads on a computer-readable medium which reads on carrier waves, which read on transitory propagating signals which are not proper patentable subject matter because they do not fit within any of the four statutory categories of invention (*In re Nuijten*, Federal. Circuit, 2006). Because the Specification includes both transitory and non-transitory media embodiments of a readable media (page 10), the claims are not statutory.

Based upon consideration of all of the relevant factors with respect to the claim as a whole, claim(s) 12-18 are held to claims reciting an abstract idea, and are therefore rejected as ineligible subject matter under 35 U.S.C. 101. The rationale for this finding is explained below:

Making reference to the *Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos* (75 FR 43922 at 43927 (27 July 2010)), factors that weigh against the eligibility of a process claim include no express or inherent recitation of a machine or transformation. Further, weighing against eligibility is a claim that is merely a statement of a general concept, such that it includes, for example, mathematical concepts such as algorithms, spatial relationships, geometry, etc…

In the instant case, claims 12-18 are not patent eligible under the *Interim Guidance* because the claims merely recite mathematical concepts of calculating a total clearance and providing a dose calculation. As such, the claims are non-statutory.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 12 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Falconnier (Journal of Gen. Intern. Med. (2001) Vol. 16, pages 369-375).

The instant claims are drawn to a method for determining a drug dose to be administered to a patient by calculating total clearance of a drug, wherein the total clearance is the sum of

renal clearance and blood filtering clearance and providing a dose calculation based on the total clearance.

In regard to claim 12, Falconnier et al. teach a method whereby dose adjustments are made for patients with renal failure based on estimation of creatinine clearance and calculation of elimination capacity for a given drug and thereby adjusting the dosing interval (page 369, column 2). Individual elimination capacity (fairly interpreted as "blood filtering clearance") was also calculated for estimation of the elimination from each individual's kidney. An adjusted dose was then calculated to yield the appropriate dosage scheme (page 370, columns 1 and 2).

In regard to claim 17, the drugs are renal secretion drugs (page 371, column 2).

2. Claims 12 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Malone et al. (Antimicrobial Agents and Chemotherapy (2001) Vol. 45, pages 3148-3155).

In regard to claims 12 and 17, Malone et al. teach calculation of total drug clearance of cefepime during continuous renal replacement therapy in critically ill patients (abstract). Malone et al teach the computerized calculation of clearance calculation during continuous arteriovenous hemofiltration (CVVH) using a patient clearance formula and a formula taking into consideration the filtration (page 3149, column 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1, 4-6, 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being obvious over Falconnier (Journal of Gen. Intern. Med. (2001) Vol. 16, pages 369-375) in view of US 2005/0102165 (Oshita et al.).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The instant claims are drawn to a drug administration support system, program and method for calculating total clearance of a drug, taking into consideration renal failure and blood filtering.

Falconnier et al. teach a method for examining the impact of immediate concurrent feedback on dose adjustment in patients with renal failure (see page 369, column 1).

In regard to claims 1, 4, 7, and 10 Falconnier teaches a method whereby dose adjustments are made for patients with renal failure based on estimation of creatinine clearance and calculation of elimination capacity for a given drug and thereby adjusting the dosing interval (page 369, column 2). Individual elimination capacity (fairly interpreted as "blood filtering clearance") was also calculated for estimation of the elimination from each individual's kidney. An adjusted dose was then calculated to yield the appropriate dosage scheme (page 370, columns 1 and 2).

In regard to claims 6 and 11, Falconnier et al. teach that the drugs are renal secretion drugs (page 371, column 2).

Falconnier et al. do not teach the storing means for blood filtering information, biological information and drug information, however, Oshita et al. teach a system, program and method for the a patient information server device that contains biological information, blood purification information (abstract) and drug information (dosage information at paragraph 0156). The system and program of Oshita et al. contain liver and kidney function information (paragraphs 0253 and 0254). Dosing conditions of drugs and biological functions (liver and kidney), as well as elimination factors and performance of blood treatments for the blood purification device are taught at paragraph 0280, as well as the display of such information.

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the calculations of Falconnier et al. for total clearance in the blood treatment systems of Oshita, as Oshita et al. actually teach incorporating such information into the system. Further, Falconnier et al. motivate one to do so at page 374, column 2, in stating that "computer assisted monitoring of drug dosing may be a promising way to reach all patients" and that "our concept of dosing can easily be used for a broad range of drugs and the ease of dose adaptation bears promising potential for integration in an electronic expert system used at the time of prescribing".

2. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being obvious over Falconnier (Journal of Gen. Intern. Med. (2001) Vol. 16, pages 369-375), as applied to claims 12 and 17 above, in view of US 2005/0102165 (Oshita et al.).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

In regard to claims 12 and 17, Falconnier et al. teach a method whereby dose adjustments are made for patients with renal failure based on estimation of creatinine clearance and calculation of elimination capacity for a given drug and thereby adjusting the dosing interval (page 369, column 2). Individual elimination capacity (fairly interpreted as "blood filtering clearance") was also calculated for estimation of the elimination from each individual's kidney. An adjusted dose was then calculated to yield the appropriate dosage scheme (page 370, columns 1 and 2). In regard to claim 17, the drugs are renal secretion drugs (page 371, column 2).

Falconnier et al. do not teach that dose calculation is supplied to a drug delivery apparatus or that is displayed. Falconnier et al. do not teach that the method involves retrieving

blood filtering information, biological information and drug information to use in the drug clearance calculation or that the method further comprises hemofiltration. However, in regard to claims 13-16, Oshita et al. teach a system, program and method for a patient information server device that contains biological information, blood purification information (abstract) and drug information (dosage information at paragraph 0156). The system and program of Oshita et al. contain liver and kidney function information (paragraphs 0253 and 0254). Dosing conditions of drugs and biological functions (liver and kidney), as well as elimination factors and performance of blood treatments for the blood purification device are taught at paragraph 0280, as well as the display of such information.

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the calculations of Falconnier et al. for total clearance in the blood treatment systems of Oshita, as Oshita et al. actually teach incorporating such information into the system. Further, Falconnier et al. motivate one to do so at page 374, column 2, in stating that "computer assisted monitoring of drug dosing may be a promising way to reach all patients" and that "our concept of dosing can easily be used for a broad range of drugs and the ease of dose adaptation bears promising potential for integration in an electronic expert system used at the time of prescribing".

3. Claims 1, 4-6, 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malone et al. (Antimicrobial Agents and Chemotherapy (2001) Vol. 45, pages 3148-3155), in view of 6,780,322 (Bissler et al.).

The instant claims are drawn to a drug administration support system, program and method for calculating total clearance of a drug, taking into consideration renal failure and blood filtering.

In regard to claims 1, 4, 6, 10, and 11, Malone et al. teach calculation of total drug clearance of cefepime during continuous renal replacement therapy in critically ill patients (abstract). Malone et al teach the computerized calculation of clearance calculation during continuous arteriovenous hemofiltration (CVVH) using a patient clearance formula and a formula taking into consideration the filtration (page 3149, column 2).

Malone et al. do not specifically teach the storing means for blood filtering information, biological information and drug information. However, Bissler et al. teach a system and method for removal of fluid from the blood of a patient by hemofiltration, hemodialysis, etc… in which the system provides a continuous flow of fluids in an extracorporeal blood circuit. In regard to system information that is taken into consideration in the system calculations, Bissler et al. teach biological information, as well as blood filtering information and drug information (column 4, lines 25-53 and column 5, lines 9-24). Bissler et al. teach a display of the information at column 11, line 55).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the drug clearance calculations of Malone et al. with the hemofiltration systems of Bissler et al. for more accurate delivery of drugs to patients in renal failure. One would have been motivated to do so because Bissler et al. teach that the system is a multipurpose system that is equipped with the infrastructure to receive independent variables from various sources as it relates to hemofiltration (column 5, lines 47-64).

4. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malone et al. (Antimicrobial Agents and Chemotherapy (2001) Vol. 45, pages 3148-3155), as applied to claims 12 and 17 above, in view of 6,780,322 (Bissler et al.).

In regard to claims 12 and 17, Malone et al. teach calculation of total drug clearance of cefepime during continuous renal replacement therapy in critically ill patients (abstract). Malone et al teach the computerized calculation of clearance calculation during continuous arteriovenous hemofiltration (CVVH) using a patient clearance formula and a formula taking into consideration the filtration (page 3149, column 2).

Malone et al. do not specifically teach the storing means for blood filtering information, biological information and drug information. However, Bissler et al. teach a system and method for removal of fluid from the blood of a patient by hemofiltration, hemodialysis, etc… in which the system provides a continuous flow of fluids in an extracorporeal blood circuit. In regard to system information that is taken into consideration in the system calculations, Bissler et al. teach biological information, as well as blood filtering information and drug information (column 4, lines 25-53 and column 5, lines 9-24). Bissler et al. teach a display of the information at column 11, line 55).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the drug clearance calculations of Malone et al. with the hemofiltration systems of Bissler et al. for more accurate delivery of drugs to patients in renal failure. One would have been motivated to do so because Bissler et al. teach that the system is a

multipurpose system that is equipped with the infrastructure to receive independent variables from various sources as it relates to hemofiltration (column 5, lines 47-64).

Prior Art Made of Record

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

1. Bohler et al. Kidney International (1999) Vol. 56, pages S-24-S-28.

2. Tucker et al. British Journal of Clinical Pharmacology (1981) Vol. 12, pages 761-770.

Conclusion

No claims are allowed.

Claims 2, 3, 8, 9, 18, and 19 appear to be free from the prior art.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

August 27, 2010
/Lori A. Clow, Ph.D./
Primary Patent Examiner
Art Unit 1631